

Docket No.: 085742-0496

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Zhengming CHEN

Patent Number: 7,202,259

Application No.: 10/714,066

Filed: November 11, 2003

For: THERAPEUTIC AGENTS USEFUL FOR TREATING PAIN

**PETITION UNDER 37 CFR 1.181**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under 37 CFR 1.181, a petition may be taken to the Director to invoke the supervisory authority of the Director in appropriate circumstances. This Petition Under 37 CFR 1.181 requests reconsideration of the patent term adjustment calculation for U.S. Patent No. 7,202,259, filed as Application No. 10/714,066 on November 11, 2003 and issued on April 10, 2007, and/or requests resetting of the date of the PTA determination for this patent so that a request for recalculation would be timely.

The U.S. Patent & Trademark Office ("PTO") permits a Request for Recalculation of Patent Term Adjustment in View of Wyeth (PTO/SB/131) for patents issued before March 2, 2010 that were not issued more than 180 days before the Request was filed. The instant patent does not fall within this time period restriction. Thus, Applicant respectfully requests that the Director exercise his authority and have the PTO recalculate the patent term adjustment ("PTA") for this patent. The arbitrary date restrictions for PTA recalculation of patents falling victim to the PTO's old, pre-

*Wyeth* calculation deprives the applicant of valuable patent term through no fault of its own. To meet the PTO's arbitrary date restriction, the applicant would have had to request recalculation based on *Wyeth* on or before October 7, 2007 (180 days after issuance), 823 days *before* the Federal Circuit decided *Wyeth*. Further, the PTO Request for Recalculation of Patent Term Adjustment in View of *Wyeth* did not come into existence until after *Wyeth*. The PTO arbitrarily decided that patents falling into the date range of the instant patent would be foreclosed from recouping the PTA they are entitled to. Respectfully, the Director should exercise his authority to remedy this injustice.

37 CFR 1.181(f) states that any petition not filed within two months of the mailing date of the action or notice from which relief is requested *may* be dismissed as untimely. Respectfully, it would be inequitable to consider this petition untimely. The decision in *Wyeth* constituted significant change in the PTO's practice sufficient to toll the deadline for filing a petition under 1.181. Courts, including the Federal Circuit, recognize the doctrine of equitable tolling, which provides that a statute of limitations should be tolled in certain circumstances in the interests of equity. See, e.g., *Sedarevic v. Advanced Med. Optics, Inc.*, 532 F.3d 1352 (Fed. Cir. 2008). The PTO should apply this judicial doctrine to the instant case. The equitable solution is to recognize the correct PTA. Denying this petition as untimely does not serve any equitable purpose – there is no balance to be weighed.

#### **Summary of Patent Term Adjustment under 35 U.S.C. § 154**

35 U.S.C. § 154 guarantees that the PTO will provide at least one notification under section 132 or a notice of allowance not later than 14 months after the date on which the application was filed, and subsequent notifications within four months of an applicant's response. PTO delays beyond these times are referred to as "A" delays.

35 U.S.C. § 154 further guarantees a no more than 3-year application pendency. This does not include time consumed by continued examination requested by the applicant. PTO delays beyond this 3-year period are referred to as “B” delays. PTO delays do not include “overlap” under 35 U.S.C. § 154(b)(2)(A). Applicant delay is deducted from the PTO delay to arrive at the PTA.

### **PTO Practice Prior to *Wyeth***

Prior to the Federal Circuit’s holding in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the PTO interpreted “no overlap” under 35 U.S.C. § 154 to mean that any A delay would necessarily result in B delay. Thus, an applicant was entitled to a PTA equal to the greater of the two types of delay, but not both.

### **The Correct Calculation under *Wyeth***

In *Wyeth*, the Federal Circuit stated that: “[n]o overlap happens unless the violations occur at the same time.” *Id.* at 1369-70. According to *Wyeth*, an applicant can be entitled to both A and B delays because no B delay occurs before the 3-year pendency date. Thus, there can be no overlap for A delays occurring before the 3-year pendency date.

### **The PTO’s Old Calculation Deprived the Applicant of 148 Days of PTA**

The PTO calculated 350 days of PTA for the instant ‘259 patent. As illustrated below, the correct calculation under *Wyeth* is 498 days. A copy of the prosecution history, downloaded from the PTO’s PAIR database is attached as Exhibit A.

(a) A Delay

(i) The instant application was filed on November 11, 2003. The PTO mailed a Requirement for Restriction on March 14, 2006. The PTO Action was 425 days beyond 14-months from the filing date, resulting in a 425 day A delay.

(b) B Delay

The '066 application was filed on November 11, 2003. The Patent Issue Date was April 10, 2007. This resulted in a B delay of 148 days as follows. Three years from November 11, 2003 is November 11, 2006. The interval between November 11, 2006 and the April 10, 2007 Issue Date is 148 days.

(c) Overlap

The overlap is the period of A delay extending beyond the 3-year pendency date into the B delay period. Here, there is no overlap.

(d) Non-overlapped PTO Delay

The A+B delay, excluding overlap, is  $425 + 148 = 573$  days.

(e) Applicant Delays

(i) Applicant delay was 46 days for the period in excess of three months from the Response to Restriction filed April 14, 2006 to the Information Disclosure Statement (IDS) filed May 30, 2006.

(ii) Applicant delayed 29 days for the period in excess of three months from the IDs filed May 30, 2006 to the October 6, 2006 Response After Non-Final Rejection.

(iii) The total applicant delay was  $46 + 29 = 75$  days.

**PTA under *Wyeth***

The correct PTA is  $573 - 75 = 498$  days.

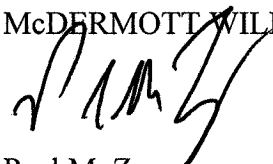
**Conclusion and Request for Supervisory Authority**

As detailed above, the '259 patent should have been granted 498 days of PTA. The PTO, using the old, incorrect calculation method, granted 350 days of PTA. Thus, the applicant was deprived of 148 days of patent term adjustment through no fault of its own. In the interest of equity, applicant requests that the Director exercise his authority to grant a recalculation of the PTA in the instant case.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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# EXHIBIT A

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10/714,066

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## Transaction History

Date	Transaction Description
11-03-2008	Change in Power of Attorney (May Include Associate POA)
10-30-2008	Correspondence Address Change
10-23-2008	Correspondence Address Change
04-10-2007	Recordation of Patent Grant Mailed
03-21-2007	Issue Notification Mailed
04-10-2007	Patent Issue Date Used in PTA Calculation
03-14-2007	Dispatch to FDC
03-03-2007	Application Is Considered Ready for Issue
02-26-2007	Issue Fee Payment Verified
02-26-2007	Issue Fee Payment Received
12-01-2006	Mail Notice of Allowance
11-29-2006	Notice of Allowance Data Verification Completed
11-29-2006	Case Docketed to Examiner in GAU
05-30-2006	Information Disclosure Statement considered
10-17-2006	Date Forwarded to Examiner
10-06-2006	Response after Non-Final Action
10-06-2006	Request for Extension of Time - Granted
05-30-2006	Information Disclosure Statement (IDS) Filed
05-30-2006	Information Disclosure Statement (IDS) Filed
06-07-2006	Mail Non-Final Rejection
06-01-2006	Non-Final Rejection
04-21-2006	Date Forwarded to Examiner
04-14-2006	Response to Election / Restriction Filed
03-14-2006	Mail Restriction Requirement
03-13-2006	Requirement for Restriction / Election
12-22-2005	Miscellaneous Incoming Letter
02-24-2005	IFW TSS Processing by Tech Center Complete
02-24-2005	Case Docketed to Examiner in GAU
04-23-2004	Application Return from OIPE
04-23-2004	Application Return TO OIPE
04-23-2004	Application Dispatched from OIPE
04-23-2004	Application Is Now Complete
04-08-2004	Additional Application Filing Fees
04-08-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant
02-12-2004	Notice Mailed--Application Incomplete--Filing Date Assigned
02-01-2004	Cleared by OIPE CSR
12-30-2003	IFW Scan & PACR Auto Security Review
11-13-2003	Initial Exam Team nn

## If you need help:

- Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail [EBC@uspto.gov](mailto:EBC@uspto.gov) for specific questions about Patent Application Information Retrieval (PAIR).
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